

### **REMARKS**

Upon entry of the present amendments, claims 163-167, 170-171, 173-180, 182-188, 190-195, 197-198, and 200-210 constitute the pending claims in the present application. Claims 1-162, 169, 172, 181, 189, and 199 were previously cancelled. Claims 168 and 196 have been cancelled herein. Claims 163-167, 170-171, 173-180, 182-188, 190-195, 197-198, and 200-206 stand rejected.

#### **Amendments**

Applicants have amended independent claims 175, 185, and 193 to more particularly define the claimed systems. Specifically, these claims have been amended to recite that the shaft has “a solid cross-section for a substantial length of the shaft.” Support for this feature can be found in the specification as originally filed, for example, from page 62, line 29 to page 63, line 6.

Applicants have also amended claims 165-167, 175-178, 180, 186-187, and 193-195 to improve clarity (“engaging member” and “engaging surface”). Applicants have also amended claim 175 to recite that “the engaging member is capable of securely engaging the engaging surface” and claim 193 to recite that the sling assembly has “an end capable of securely engaging the engaging member of the shaft.” Support for these amendments can be found throughout the specification as originally filed, for example, on page 12, lines 22-25; page 13, lines 12-14; page 62, lines 2-3 and 19-20; page 63, lines 3-4; and page 64, lines 15-17, and 29-31, among others, as well as in Figures 69-74, which depict secure engagement of the sling assembly detachable member 1424 to the shaft 2014.

Applicants have also amended claim 185 to recite that the sling assembly has “an end capable of fitting over the distal end of the shaft.” Support for this amendment can be found at least in Figures 74-75, which depict the detachable member 1424 of the end of the sling assembly fitting over the distal end of the shaft 2014.

Applicants have also added new claims 207-210. Support for these claims can be found in the original specification, at least from page 4, line 31 to page 5, line 1; on page 5, lines 19-22; page 10, lines 1-2; page 33, lines 26-27; and page 35, lines 20-22.

Applicants assert the above amendments and new claims present no new matter and reserve the right to file one or more continuing applications directed to the claims as unamended.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Office will be addressed below in the order they appear in the Office Action.

Withdrawal of Prior Rejections of Record

Applicants note with appreciation the withdrawal of prior rejections of record over various combinations of U.S. Patent No. 5,336,231 to Adair, U.S. Patent No. 4,935,027 to Yoon, and Norris et al. "Use of Synthetic Material in Sling Surgery: A Minimally Invasive Approach" ("Norris").

Summary of Telephonic Interview

Applicants appreciate the time and attention of Examiner Lacyk during the telephonic interview of December 30, 2008. During the interview, the instant rejection of claim 163 under 35 U.S.C. 112 was discussed, and Applicants highlighted the portions of the original application that support the feature "for covering only partially the sling," and the Examiner indicated that he would consider these portions. The present rejection of claim 175 over U.S. Patent No. 5,439,467 to Benderev et al. ("Benderev") in view of Norris was discussed, and agreement was reached that claim 175 as currently amended distinguishes over the cited art since the Benderev probe guide 125 and the combination of the probe guide and the probe 115 do not have a solid cross section because the probe must slide within the probe guide for the Benderev device to function properly and because the probe 115 by itself cannot securely engage the Benderev suture 165 (the alleged sling assembly) (*vide infra*). The outstanding rejection of claim 163 over Benderev in view of Norris and further in view of U.S. Patent No. 3,580,256 to Wilkinson et al. ("Wilkinson") was also discussed, and Applicants presented remarks (*vide infra*) on why a *prima facie* case of obviousness has not been established. The Examiner responded that such remarks might overcome the rejection if presented in a Reply.

Accordingly, the remarks below respond to the outstanding rejections in light of the substance of the telephonic interview.

Claim Rejections – 35 U.S.C. 112 – Claims 163-168, 170-171, 173-180, 182-184, 186-187, 190-198, and 200-206

Claims 163-168, 170-171, 173-180, 182-184, 186-187, 190-198, and 200-206 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. While Applicants disagree with the Office's position, Applicants have cancelled claims 168 and 196 to expedite prosecution, and so the rejection is rendered moot for these claims. For the remaining rejected claims, Applicants respectfully traverse the rejection.

The Office contends that there is no support in the application as originally filed for "a pouch for covering only partially the sling" as recited in claims 163, 182, 190, and 200. Applicants respectfully disagree and direct the Office's attention to page 32, lines 19-21 and Figures 15 and 22 of the application as originally filed. This passage describes the sling 216 as being covered only partially by the pouch 214 since the sling 216 extends beyond the proximal end 224 of the pouch 214 "to permit the proximal end 226 of the sling to be grasped or secured." As can be seen in Figure 15, the sling 216 is depicted as being covered only partially by the pouch 214 since the former extends beyond the coverage of the latter, and as seen in Figure 22, the portion of the sling that extends beyond the pouch is shown being grasped by forceps. Additional support can be found in Figure 20, which depicts how a sling (not pictured) would be only partially covered by the pouch 414 as a result of exposure by pores/apertures 411 in the pouch. More support is located in Figures 51 and 60-61, which depict the sling 1211 being covered only partially by the pouch 1214, i.e., where the end portion of the sling 1211 extends beyond the pouch 1214 and where the pouch is exposed/not covered as a result of apertures 1218. Hence, Applicants assert that one of skill in the art would have appreciated that Applicants indeed had possession of "a pouch for covering only partially the sling" at the time of filing the instant application. Accordingly, Applicants request reconsideration and withdrawal of the rejection as pertains to these claims and those dependent thereon.

The Office also rejects claims 165-167 and 193-195 for reciting a "channel" feature and claim 175 (and presumably claims 176 and 180 as well) for reciting an "interlocking mating structure." While Applicants disagree with the Office's position, in order to expedite prosecution,

Applicants have amended these claims and also claims 177-178 and 186-187 as noted above such that they now recite an “engaging member” and, in some instances, “an engaging surface.” As such, Applicants request reconsideration and withdrawal of the rejection of these claims and those dependent thereon.

Claim Rejections – 35 U.S.C. 103(a) – Claims 175-180, 185-188, 193-198 over Benderev in View of Norris

Claims 175-180, 185-188, 193-198 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benderev in view of Norris. Applicants traverse the rejection to the extent that it is maintained over the claims as amended.

Pursuant to MPEP 2142:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants’ disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

For the following reasons, Applicant’s assert that Benderev and Norris, either alone or in combination, fail to teach or suggest all of the features of claims 175, 185, and 193 as currently amended, and so these references cannot render obvious these claims or those dependent thereon.

The Office relies on Benderev for the “shaft that has a curved portion and a distal end.” However, Benderev does not teach or suggest “a shaft having a solid cross-section for a substantial length of the shaft...” as recited in claims 175, 185, and 193 as currently amended. As seen in Figures 2-4 of Benderev, the Benderev “shaft” (the probe guide 125) is hollow, which is necessary in order to house and cooperatively work with the probe 115 (see Benderev Abstract). The use of a probe guide with a solid cross-section, instead of the hollow one that Benderev illustrates, would render the Benderev device unusable by making it incompatible with the probe 115, so the probe guide 125 of Benderev cannot be said to teach or suggest the use of a shaft having a solid cross-section for a substantial length of the shaft.

Similarly, were the Office to consider the *combination* of the Benderev probe 115 and the probe guide 125 to satisfy the shaft of claims 175, 185, and 193, Applicants respectfully submit that any such combination also cannot have a solid cross-section as the probe must slide within the probe guide, and this requires a hollow space. As such, the combination of the Benderev probe 115 and the probe guide 125 also does not teach or suggest the shaft of claims 175, 185, and 193.

To the extent that the Office considers the Benderev probe 115 to be the shaft recited in the pending claims, Applicants highlight that as applied to claim 175 the probe 115 does not include an engaging member capable of securely engaging the engaging surface of a sling assembly. While the Benderev probe 115 includes a slotted recess 160, this is not capable of securely engaging the suture 165 since the suture would simply fall away if placed into contact with the slotted recess without any other fastening.

A similar analysis holds for claim 193. This claim recites “a sling assembly comprising ... an end capable of securely engaging the engaging member of the shaft.” Yet Benderev does not teach or suggest that the suture 165 (the alleged sling assembly) possesses an end capable of securely engaging the probe 115. This is because the Benderev suture 165 does not perform any secure engaging; rather, its role is passive as it is grasped by the combination of the probe and probe guide 125 (see column 7, lines 9-14 of Benderev). Hence, the Benderev suture 165 cannot satisfy the role of the sling assembly recited in claim 193.

Regarding claim 185, this claim recites “a sling assembly comprising ... an end capable of fitting over the distal end of the shaft.” However, Benderev does not teach or suggest that the suture 165 (the alleged sling assembly) is capable of fitting over the probe 115, and Figure 2 of Benderev demonstrates that the suture 165 remains on one side of the probe. Thus, the Benderev suture 165 cannot satisfy the role of the sling assembly recited in claim 185.

Since Benderev and Norris, either alone or in combination, fail to teach or suggest all of the features of claims 175 (e.g., the shaft and/or the engaging member of the shaft capable of securely engaging the engaging surface of the sling assembly), 185 (e.g., the shaft and/or the sling assembly end capable of fitting over the distal end of the shaft), and 193 (e.g., the shaft and/or the sling

assembly end capable of securely engaging the engaging member of the shaft), these references cannot render obvious these claims or those dependent thereon. *Vaeck, supra*. Accordingly, Applicants request reconsideration and withdrawal of the rejection.

Claim Rejections – 35 U.S.C. 103(a) – Claims 163-168, 170-171, 173-174, 182-184, 190-192, 200-206 over Benderev in View of Norris in Further View of Wilkinson

Claims 163-168, 170-171, 173-174, 182-184, 190-192, 200-206 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benderev in view of Norris and further in view of Wilkinson. Applicants traverse the rejection to the extent that it is maintained over the claims as amended.

The Office relies on Wilkinson to satisfy the “pouch” feature in the present claims. However, the combination of Wilkinson with Benderev and Norris fails to establish a *prima facie* case of obviousness because one of ordinary skill in the art would not have been motivated to make this combination and would not have had a reasonable expectation of success in doing so.

Firstly, the Office asserts that the combination of Wilkinson with Norris would have been obvious because “pouches or sleeves were commonly used in the art at the time of the invention to protect the body from implanted materials and objects.” The Office has not provided evidence in support of this statement. Applicants highlight that Wilkinson does not teach that “pouches or sleeves were commonly used in the art at the time of the invention to protect the body from implanted materials and objects” because the alleged pouch of Wilkinson, the coating 13, is not implanted in the body. Rather the coating 13 is provided to temporarily fix a preformed semi-knot to “speed up the tying of a knot” by a surgeon (see Wilkinson, column 1, lines 1-20). But in order for the knot to be completely tied, the coating 13 must tear apart (see Wilkinson, column 2, lines 1-5, 16-20, and 30-35) and be removed from the suture. Since the coating 13 is removed on completing the knot, which must happen before the knot is implanted into the body, the coating is no longer present when the knot is implanted, and so no coating is ever implanted. Hence, the alleged motivation submitted by the Office is not supported by Wilkinson.

If “pouches or sleeves were commonly used in the art” of urinary incontinence to partially cover slings at the time of filing, then Applicants respectfully request that such art be made of

record. Without such evidentiary basis, the Office's claim that one of ordinary skill would have been motivated to combine is without support and thus untenable.

Moreover, Applicants submit that the explicit teachings of Wilkinson and Norris do not support a motivation to combine. As taught throughout Wilkinson, the alleged "pouch" (again, more accurately "a thin film coating ... formed by dipping or spraying" – see column 1, lines 60-61 of Wilkinson) is used to cover a suture, which the Office considers "sling material" (see page 4, third whole paragraph of the outstanding Office Action). In contrast, Norris discloses a Gortex patch (see first line under "Technique"), which the Office considers "a sling that has a flat shape" (see paragraph spanning pages 3-4 of the outstanding Office Action). While Applicants generally disagree with this broad and inconsistent interpretation of what constitutes a "sling," Applicants specifically highlight that one of skill in the art would not have considered the Wilkinson suture and the Norris Gortex patch to be equivalent or even interchangeable, and as a result, one would not have applied any "pouch" on the Wilkinson suture to the Norris patch. As taught by Norris, the Gortex patch provides a supporting surface area for supporting a urethra. In contrast, the Wilkinson suture is just that, a thin wire for stitching two tissues together, not taught or suggested by either Wilkinson or Norris to support a urethra. Furthermore, Norris distinguishes between the Gortex patch and a suture (see second paragraph under "Technique"), thus informing one of skill that these are different and not interchangeable. Accordingly, the Gortex patch of Norris and the suture of Wilkinson are taught to have completely different structures and purposes, and correspondingly the skilled artisan would not have been motivated to apply Wilkinson's suture modification to Norris' patch.

Furthermore, considering the large differences in structure and purpose between the Norris Gortex patch and the Wilkinson suture, the skilled artisan would not have been motivated to search outside Norris' field of urinary incontinence for the non-analogous art of Wilkinson for modification of a non-suture-like structure, such as the Norris patch. The benefits of the coating taught by Wilkinson (retention of a suture in a pre-formed knot configuration) are unhelpful in the use of the Norris patch, and, as noted above, Wilkinson does not teach or suggest use of the coating

to “protect the body from implanted materials and objects.” These findings further underscore that Wilkinson is non-analogous art with respect to Norris.

Additionally, as the Wilkinson suture and the Norris patch are so disparate in structure and purpose, one of ordinary skill would not have had a reasonable expectation of success in combining the Wilkinson “pouch” with the Norris patch. The Wilkinson “pouch” is simply a coating sprayed onto a suture formed into a preformed partial knot (see column 1, lines 22-24). Such a “wax or plastic” coating would completely block the interstices and pores within the Gortex patch. Yet, such pores are the hallmark of the breathable Gortex fabric and facilitate the patch’s absorption of antibiotic solution (see Norris, last line of second paragraph under “Technique”). Furthermore, the Gortex fabric is flexible, facilitating implantation and acceptance by the patient’s body, but a coating of wax or plastic would likely stiffen the patch and render it less flexible for urethral support. In addition, Wilkinson describes the coating as being “soft or frangible to tear apart or disintegrate” (see column 2, lines 2-3). The skilled artisan would not desire pieces of wax or plastic to break and dislodge from the Office’s suggested coated patch and remain within the pubo-urethral area of the patient or complicate surgical implantation. As noted above, this is not a problem in Wilkinson because the coating is removed on completion of the knot, which precedes implantation into the body. Considering the possible ways modification of the Norris Gortex patch with the coating of Wilkinson could lead to an inferior or dangerous product, one of ordinary skill in the art would not have had a reasonable expectation of success and would not have been motivated to attempt such a combination.

Accordingly, the motivation and reasonable expectation of success requirements for establishing a *prima facie* case of obviousness have not been established, *Vaeck, supra*, and Applicants request reconsideration and withdrawal of the rejection of claims 163-168, 170-171, 173-174, 182-184, 190-192, 200-206.

### CONCLUSION

In view of the above arguments and amendments, Applicants believe the pending application is in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000.


Reply dated January 12, 2009  
In Reply to Office Action of August 11, 2008

Application No.: 10/774,826  
Docket No.: MIY-P03-006

Applicants believe no fee beyond that required for the above-mentioned extension of time is due with this response. However, if an additional fee is due, please charge our Deposit Account No. 18-1945, under Order No. MIY-P03-006 from which the undersigned is authorized to draw.

Dated: January 12, 2009

Respectfully submitted,

By   
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